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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,252	04/02/2004	David Walter Wright	115624	8511
25944 7590 11/18/2008 OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850				
EXAMINER				
BOWERS, NATHAN ANDREW				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
11/18/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/816,252

**Applicant(s)**

WRIGHT ET AL.

**Examiner**

NATHAN A. BOWERS

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 31-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 56-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gremel (US 6918887) in view of Pawlak (US 5674397).

With respect to claim 1, Gremel discloses an apparatus for separating gas from a liquid path comprising a chamber (Figure 4:30) having a top, bottom and side walls. A first opening (Figure 4:44) allows gas and liquid to enter the chamber, a second opening (Figure 4:34) is configured to allow gas to exit the chamber, and a third opening (Figure 4:48) is configured to allow liquid to exit the chamber. This is taught in column 2, line 46 to column 3, line 11. Figure 4 shows that the second opening is located in a middle portion of the top of the chamber, and that the third opening is located in a middle portion of the bottom of the chamber.

Gremel, however, also does not expressly indicate that each of the openings and corresponding channels are formed within the walls of the surrounding housing. Rather, Gremel teaches that the openings and channels are formed as separate structures that are positioned exterior to the housing inner volume.

Pawlak discloses a debubbler that comprises a chamber housing defining a chamber (Figure 15:1029) capable of holding a liquid and gas. Openings and channels are cut into the sidewalls of the housing in order to allow the ingress and withdrawal of fluid and gas streams. This is disclosed in column 27, line 44 to column 28, line 4. Gas and liquid are separated by a membrane (Figure 15:1006), and degassed fluid is removed from one opening (Figure 15:1020) while gas is removed from another opening (Figure 15:1018).

Gremel and Pawlak are analogous art because they are from the same field of endeavor regarding gas-liquid separation systems.

At the time of the invention, it would have been obvious to form the tissue transporter disclosed by Gremel as a housing that includes openings and channels cut into the sidewalls. Pawlak teaches that this configuration is well known in the art, and is suitable for the effective

removal of gases and liquids. The creation of channels formed as cavities within the solid housing and the creation of channels formed as autonomous units exterior to the chamber volume interior represent functionally equivalent means for adding and withdrawing fluid from the chamber. It would have required only minor structural alterations to the existing Gremel housing to provide channels and openings similar to those disclosed by Pawlak, and this alteration would have been accomplished in a predictable manner.

With respect to claims 2-4, Gremel and Pawlak disclose the apparatus in claim 1 wherein the chamber is located within a housing. The outer shell of the chamber walls is considered to represent a housing such that the first, second and third openings cause fluid to move through the chamber and housing.

With respect to claim 12, Gremel and Pawlak disclose the apparatus in claim 3 wherein tubing is connectable to each of the plurality of openings. This is apparent from Figure 3.

2) Claims 1-12, 18-30, 56-58 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 20040029266) in view of Pawlak (US 5674397).

With respect to claims 1-3 and 56, Barbera-Guillem discloses a tissue transporter (Figure 1:100) comprising a chamber (Figure 1:170) that includes a top, bottom and side surfaces. A first opening (Figure 33:300) is configured to allow liquids and gases to enter the chamber, and a second opening is provided in communication with a tubing (Figure 33:498) to remove gas from the chamber. This is disclosed in paragraphs [0262] and [0263]. From Figure 33, it appears that

the second opening is provided in a middle portion of the top of the chamber. If the second opening is not provided in a middle portion of the top of the chamber, it would have been obvious to position the second opening at this location. The selection of an exact area to situate a gas outlet at the top of a container is merely a design choice arrived at through a simple rearrangement of parts. Although Barbera-Guillem does not provide a Figure in which a third opening is provided, it would have been obvious to provide additional openings through which liquids could be removed. Paragraph [0058] states that at least one inlet/outlet is provided, thereby strongly implying that it would have been obvious to include a third opening similar to the first opening capable of removing liquids from the chamber. It would have been to ensure that this third opening is situated at the middle portion of the bottom of the chamber if it was determined that this location resulted in the most effective removal of fluids from the chamber.

Barbera-Guillem, however, also does not expressly indicate that each of the openings and corresponding channels are formed within the walls of the surrounding housing. Rather, Barbera-Guillem teaches that the openings and channels are formed as separate structures that are positioned within the housing inner volume.

Pawlak discloses a debubbler that comprises a chamber housing defining a chamber (Figure 15:1029) capable of holding a liquid and gas. Openings and channels are cut into the sidewalls of the housing in order to allow the ingress and withdrawal of fluid and gas streams. This is disclosed in column 27, line 44 to column 28, line 4. Gas and liquid are separated by a membrane (Figure 15:1006), and degassed fluid is removed from one opening (Figure 15:1020) while gas is removed from another opening (Figure 15:1018).

Barbera-Guillem and Pawlak are analogous art because they are from the same field of endeavor regarding gas-liquid separation systems.

At the time of the invention, it would have been obvious to form the tissue transporter disclosed by Barbera-Guillem as a housing that includes openings and channels cut into the sidewalls. Pawlak teaches that this configuration is well known in the art, and is suitable for the effective removal of gases and liquids. The creation of channels formed as cavities within the solid housing and the creation of channels formed as autonomous units within the chamber volume interior represent functionally equivalent means for adding and withdrawing fluid from the chamber. It would have required only minor structural alterations to the existing Barbera-Guillem housing to provide channels and openings similar to those disclosed by Pawlak, and this alteration would have been accomplished in a predictable manner.

With respect to claims 4-9, Barbera-Guillem and Pawlak disclose the apparatus in claim 3 wherein the that openings located on the housing are situated upon a common plane of the same sidewall. Although Barbera-Guillem shows that the openings are located near a top of the same side surface, it would have been obvious to locate each opening on the sidewall according to any predetermined arrangement.

With respect to claims 10, 57 and 58, Barbera-Guillem and Pawlak disclose the apparatus in claims 2 and 56 wherein the housing is in communication with the inner chamber which functions as a tissue transporter.

With respect to claim 11, Barbera-Guillem and Pawlak disclose the apparatus in claim 2 wherein at least part of the housing is transparent. This is disclosed by Barbera-Guillem in paragraph [0057].

With respect to claims 12 and 18, Barbera-Guillem and Pawlak disclose the apparatus in claim 3 wherein tubing is connectable to each of the plurality of openings. This is apparent from Figure 33.

With respect to claims 19-30, Barbera-Guillem and Pawlak disclose the apparatus in claim 4 wherein entrance and exit channels (Figure 33:500 and Figure 33:496) are used to connect each housing opening with a respective chamber opening. Figure 33 indicates that the first housing opening is at a top portion of the housing and that the first chamber opening is at a bottom portion of the chamber. Figures 32 and 33 show that portions of the entrance and exit channels are curved, and that some portions of the entrance and exit channels are approximately horizontal and others approximately vertical. It would have been obvious to construct the entrance and exit channels according to any desirable shape or size that resulted in the most effective fluid transfer to and from the chamber.

With respect to claim 64, Barbera-Guillem and Pawlak disclose the apparatus in claim 58. Furthermore, the housing and tubing of Barbera-Guillem are considered to be fully capable of being connected to a tube frame and an organ transporter.



3) Claims 13-17 and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 20040029266) in view of Pawlak (US 5674397) as applied to claims 12 and 58, and further in view of Sadri (US 5494822).

Barbera-Guillem and Pawlak disclose the apparatus set forth in claims 12 and 58 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly state that a sensor is provided for detecting gas moving through the first and/or third housing openings.

Sadri discloses a device for transporting and maintaining an organ that comprises a chamber (Figure 1:25) for holding the organ, a fluid supply line (Figure 1:13) and an oxygenator (Figure 1:6). This is disclosed in column 10, line 34 to column 11, line 6. Column 6, lines 11-20 further state that a bubble trap is provided between the oxygenator and the perfused organ. Sensors (Figure 1:14) monitor gas levels of fluid moving from the bubble trap to the organ chamber. Column 11, lines 50-58 state that the flow rate of perfusate flowing into the organ is altered in response to gas level characteristics measured in the fluid. Column 7, lines 40-60 indicate that the operation of the pumping mechanisms and valves regulating the fluid system are controlled in response to measurements made by the gas sensors. Although Sadri does not specifically disclose the use of an ultrasonic gas sensor, ultrasonic gas sensors are considered to be well known in the art. It would have been obvious to use any known sensor in the apparatus of Sadri.

Barbera-Guillem and Sadri are analogous art because they are from the same field of endeavor regarding tissue culture means.

At the time of the invention, it would have been obvious to equip the apparatus of Barbera-Guillem with a gas monitoring probe capable of interacting with a control system

designed to regulate fluid flow to and from the tissue/cell culture in response to detected gas levels. Sadri teaches that it is important to maintain appropriate gas levels within a tissue perfusion device in order to sustain conditions suitable for cell growth. Automated systems are beneficial because they are accurate, cost effective and reliable.

*Response to Arguments*

In response to Applicant's amendments all previously set forth rejections under 35 U.S.C. 112 have been withdrawn.

Applicant's arguments filed 28 August 2008 with respect to the 35 U.S.C. 102 rejections involving Fahy have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments filed 28 August 2008 with respect to the 35 U.S.C. 102 rejections involving Gremel have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Gremel and Pawlak.

Pawlak addresses the deficiencies of Gremel by indicating that it is known in the art to create liquid-gas separation means using first, second and third openings formed in the sidewalls of a chamber housing.

Applicant's arguments filed 28 August 2008 with respect to the 35 U.S.C. 103 rejections involving Barbera-Guillem have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Barbera-Guillem and Pawlak.

Pawlak addresses the deficiencies of Barbera-Guillem by indicating that it is known in the art to create liquid-gas separation means using first, second and third openings formed in the sidewalls of a chamber housing.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1797

/Nathan A Bowers/  
Examiner, Art Unit 1797